SUMMARY OF THE
ANIMAL FEED SAFETY SYSTEM (AFSS)
PUBLIC MEETING, September 23-24, 2003
Hyatt Dulles International Airport, Herndon, VA

Submitted to: Dr. George Graber
AFSS Team Leader
CVM/FDA

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PURPOSE OF PUBLIC MEETING: To discuss the potential development of a comprehensive, risk-based Animal Feed Safety System (AFSS) describing how animal feeds (including ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and people consuming food products from animals.

The meeting featured stakeholder and government speakers discussing safety measures currently in use and others which could be adapted to the feed industry. In addition, the meeting included several facilitated breakout discussion groups.

AGENDA: The program for the two day meeting consisted of introductory and opening remarks by CVM personnel, lecture type presentations from seven people, breakout study groups, and concluded with reports from breakout study groups. (Below is a retyped copy of the revised agenda.)

<u>September 23</u>

1:00 – 1:05 p.m.	Dr. George Graber, CVM – moderator
1:05 – 1:10 p.m.	Dr. Clifford Johnson, CVM – comments
1:10 – 1:30 p.m.	Dr. Stephen Sundlof, CVM – opening remarks
1:30 – 1:50 p.m.	Tim Costigan, Prince Agri Products – ingredient manufacturer, minerals
1:50 – 2:10 p.m.	Dave Harlan, Excel – ingredient manufacturer, rendering company
2:10 – 2:30 p.m.	Joe Garber, Wenger Feeds – feed manufacturer
2:30 – 2:50 p.m.	Break
2:50 – 3:10 p.m.	Mike Merkel, Doane Pet Care – pet feed company
3:10 – 3:30 p.m.	Mike Davidson, California Department of Food and Agriculture – State feed safety regulatory program
3:30 – 3:50 p.m.	Dennis Byrne, Herr Angus Farm
3:50 – 4:10 p.m.	Dr. Richard Wood, Food Animal Concerns Trust – consumer perspective
4:10 – 4:30 p.m.	Break
4:30 – 4:45 p.m.	Gloria Dunnavan – Explanation of Breakout Groups
4:45 – 5:30 p.m.	Meeting of Breakout Groups

6:00 – 8:00 p.m.	Reception

September 24

7:00 – 8:00 a.m.	Continental Breakfast
8:00 – 9:30 a.m.	Meeting of Breakout Groups
9:30 – 9:45 a.m.	Break
9:45 – 10:45 a.m.	Meeting of Breakout Groups, continued
10:45 – 11:00 a.m.	Break
11:00 a.m. – 12:00 noon	Reports by Breakout Groups
12:00 noon – 1:00 p.m.	Lunch (provided)
1:00 – 2:30 p.m.	Reports by Breakout Groups, continued
2:30 – 2:45 p.m.	Break
2:45 – 3:00 p.m.	Next Steps

ATTENDANCE AND PARTICIPATION: Attendance was high and participation was good. This indicated great interest and importance in the topic for the meeting. Participants were from various segments of the overall feed industry in the U.S., state and federal agencies, universities, and the media. (Below is an unofficial list of 212 registrants.)

Audrey Adamson
Nikhil Agarwal
David C. Ailor
Doug Anderson
Dr. Frederick J. Angulo
Jeffrey C. Archer
Bruce Arentson
Paul M. Bachman
Brenda Ball
Regina Barrell
Dr. Neal Bataller
Robert L. Beine
Kim Bell
Greg Bergt
Samuel Beverly
Dr. Fred Bisplinghoff
James W. (Jim) Blakely
Wayne Bomgarden
Warren R. Bontoyan
David Bossman
Dr. Johnny Braddy
John W. Breitsman
Dr. Roy Brister
Bob Broyles
Rebecca Buckner
Brian L. Bursiek
Dennis Byrne
Jan Campbell
Sue Carlson
Dr. Tom Chiller
Dr. George Clark
Tony L. Claxton
Nancy K. Cook
Thomas M. Cook
W. Marcus Cooke
Bruce G. Cooper
Michael E. Cooper
Tim Costigan
Constantine V. Cotsoradis
Dr. Andrew Cupit
Kevin Custer
Michael Davidson
Ron F. Demory
Dr. Linda A. Detwiler
Gail Dixon
Jack Douglas
J.W. Dunlap
Gloria Dunnavan
Edward D. Edmiston
David A. Eisenberg
Duane Ekedahl
Karen B. Ekelman
Dr. Henry Ekperigin
David Fairfield
Michael D. Fanning
Dr. Don A. Franco
Tom Frost
Joe Garber
Patsy Gardner
Robert Geiger
Dr. Katerina Geronian
Zoe Ann Gill
Laura Gilcrest
William B. Goodman
Janice M. Gordon
Randall C. Gordon
Brad Gottula
George Graber
Linda A. Grassie
David Grau
Andy Gray
Jo W. Gulley
Mark Hackman
Richard Halda
Mary Hagler
Jean Halloran
C. Ross Hamilton
Alan R. Hanks

Michael Hansen
Chandra Hardwick
David W. Harlan
Lots Hartstein
George W. Hayslip
Tim Herrman
Lance Hester
James H. Hodges
Roger D. Hoestenbach
Jim Hogue
Robert Hopkins
Ruth A. Hoskins
William C. Hughes
Ken Jackson
Terry L. Jensen
A. Bruce Johnson
Clifford I. Johnson
Yvette Johnson
Jamey Johnson
Ben Jones
Shannon Jordre
Jeri Kahana
Ibrahim Kamara
Alt Kashani
Dan King
Sandy King
David Kirstein
Don Kouse
Kerry Krom
Mike Langenhorst
Leon Law
John Lienesch
Robert C. Livingston
Penny Marsh
Steve Martin
Daniel G. McChesney
Dr. John Dennis McCurdy
Diane R. McDaniel
David Mednick
Michael W. Merkel
Michael Meyers
Dianne H. Milazzo
Dr. Eli Miller
Dragan Momcilovic
Barbara Montwill
Linda Morrison
Dr. San Myint
Kenny Naylor
Eric Nelson
Ronald Newman
Dr. Dawn Norton
Richard O'Hara
Michael 0'Meara
Roger Osburn
Harwood W. Owings III
Jacquelyn L. Pace
Dr. Joseph Paige
Katrine Parmley-Gates
Stephen Payne
Dr. Gary Pearl
David G. Peek
Fran Pell
Betty Pendleton
Marlene Petersen
Philip K. Petry
Keith Pike
Darlene Plank-Turlington
Isabel W. Pocurull
Glenn Pratt
Stephen Pretanik
Carla J. Price
Charles Price
Gerardo A. Ramirez
Eliezer Ramos
Ralph Randall
Dr. Jim Rasekh
Lars Reimann
Michael E Rempe
C. Reed Richardson
Kurt Richardson
Karen Robles
Barbara Rodgers
Dr. Tina I. Rouse
Rex A. Runyon
Dr. Louis Russell
Jim Rydell
Randy Sample
Jon Scheid
Ron Scherzberg
Roger Scholten
Sally Schuff
Richard Sellers
Greg Sherwood
Virgil Sinning
Steven A. Skaar
Kristi 0. Smedley
Gerald F. Smith, Jr.
Charles Stark
Zaira Steele
Richard G. Stoll
Mike Stott, Sr.
Dr. Stephen F. Sundlof
Kent Swisher
David Syverson
Richard Ten Eyck
David Thain
Tamiko Thomas
Angele Thompson
Dr. Linda Tollefson
Bill Tomson
Steve L. Traylor
Marc Travillian
Phil Trefsgar
Arthur Y. Tsien
Sarah Tyree
Richard Uncles
Gina Valeri
Mr. Mel Vanden Berg
Alton A. VanDyke
Madeline Vanhoose
Roger C. Viadero
Dr. David Wagner
Garry W. Wagner
Steve Wawrzyniak
Sondra Wenderoth
Caren Wilcox
Cecil Williams
Dick Wilson
Robert R. Wilson
Wondu Wolde-Mariam
Dr. Richard Wood
Toni Wooten
Jerome G. Woyshner
Kim R. Young

OUTLINE SUMMARY

Following is a summary in outline style consisting of major and/or distinguishing aspects of the presentations, and the breakout study groups, followed by a general conclusion statement.

PRESENTATIONS: Seven (7) speakers representing feed industry businesses or state/federal agencies delivered twenty minute presentations in their respective areas. Each presentation is summarized in the order as presented on the agenda:

1. **Tim Costigan**, Prince Agri Products – ingredient manufacturer, minerals.
   - **a.** Presented a flow diagram of their premix system which included quality assurance features of controlled formulations, computer controlled ingredient additions, manual double checks, and electronic scale records
   - **b.** Discussed their production system checks which consisted of two categories:
     - ?? Raw materials
       - Basis for ingredient specifications
       - Schedule for inbound ingredient sampling and retention of samples
       - Criteria and frequency of chemical and physical analysis
     - ?? Production process
       - Appearance check
       - Batch yields
       - Periodic analysis
       - Batch samples retained for one year
       - Magnet inspection
       - Inventory reconciliation
   - **c.** Ingredient evaluation was discussed in respect to two components
     - ?? Required analysis for zinc oxide
       - ZN formulated value
       - Pb, Cd, As (process issue)
     - ?? Annual review
       - Analysis listed above
       - ZN metal (process issue)
       - Dioxin (known hazard)
       - Scan for 70 trace elements, densities, particle size, and moisture
   - **d.** Traceability was addressed with three main groupings of information collected
     - ?? Records
       - Controlled distribution traceable through item number/lot number
     - ?? Ingredients
       - Resale ingredients, consumed macro, and consumed micro ingredients traceable by supplier's or applied lot numbers
   - **e.** Biosecurity procedures were presented as related to visitor monitoring, employee background checks and training, and security and inspection of feed material
   - **f.** Contamination concerns were addressed under chemical microbial/biological, and physical materials

g. Safety audits were discussed as preformed in two categories as related to responsibilities of production personnel (safety audits, sanitation audits, procedural audits, dock audits), and the quality unit (annual comprehensive audits, and annual formulations audit).

h. Overall quality program

?? Apply portions of existing programs that apply
- HACCP for risk assessment
- ISO for document control, procedures
- GMP for hygiene, traceability, and contamination issues

?? Focus on preventative measures
- Ingredient quality
- Process evaluation
- Confirmation testing

2. **Dave Harlan**, Excel – ingredient manufacturer, rendering company.

a. Presented a concept flow diagram of food animal production components including feed ingredients, feed manufacturing, meat processing, rendered co-products, and consumer foods

b. Discussed a flow diagram of their rendering process which included offal and bone/fat mixing and grinding, the cooking procedure, and product separation into solid and liquid streams

c. Comprehensive program at their facility was described

?? Philosophy and commitment
?? Raw material source, specifications and assurances
?? Hazard Analysis and Critical Contact Point program
?? Good Manufacturing Practices
?? Employee training programs
?? Transportation policy
?? Third policy audits

d. Described their specifications used for raw materials

?? In-house packer house source – 70% mature cows and 30% fed cattle
?? 100% of cattle pass USDA/FSIS ante mortem inspections
?? Packing house training relative to physical and chemical contaminants
?? Central nervous system tissue removed in packing house

e. Listed seven (7) principles of HACCP

?? Assess hazards
?? Determine critical control points – CCP
?? Establish critical limits for CCP's – CCPCL
?? Procedures to monitor CCP's
?? Develop corrective action plans
?? Recordkeeping
?? Verification

f. Described potential hazards in three (3) classes

?? Biological – microbiological, insects, TSE's
?? Chemical – pesticides, PCB's, lubricants, oils, etc.

?? Physical – metal and plastic

g. Presented general procedures for microbial/pasteurization HACCP program

h. Outlined a GMP example used to prevent salmonella recontamination
- ?? AAPI model adopted by 99% of industry
- ?? Process zones in facility
- ?? Work habits and policies
- ?? Startup procedures
- ?? Reprocessing of product spills
- ?? Dry cleaning of finished product areas
- ?? Sanitation practices that target "hot spots"
- ?? Facility design and equipment maintenance
- ?? Effectiveness verified by finished product testing

i. Addressed procedures in place related to their transportation policy
- ?? Certification of carriers
- ?? Use trucks that only haul agricultural commodities
- ?? Trucks are to be cleaned prior to arrival
- ?? Visual inspection of empty trucks to control carryover of past ingredients
- ?? Assurance of cleanout policy signed by carriers and drivers

3. Joe Garber, Wenger Feeds – feed manufacturer

a. Presented an overview about their quality assurance program, HACCP – what it's good for and why they did it, and the next step in the Wenger System

b. Quality assurance program consists of the following components
- ?? Product design and labeling
- ?? Ingredient selection from approved suppliers list
- ?? Production scheduling to include flushing and sequencing
- ?? Manufacturing to include work instructions and preventive maintenance
- ?? Delivery

c. HACCP program consists of the following components
- ?? Comprehensive risk analysis, focus on potential human food related illness risk factors
- ?? Over 150 man hours spent identifying potential risks
- ?? Formal system for identifying risks and tracking non-conformances
- ?? Identifying "weak spots" in our system and providing the tools to fix them

d. Described the management system in place at their company consisting of the following components
- ?? A frame work for managing on organization's significant environmental, safety and quality aspects, which placed reliance on a systems approach, not on individuals
- ?? Holistic management and total employee involvement
- ?? Proactive vs. reactive thinking
- ?? Regulatory (GMP's)
- ?? Quality (ISO 9001)
- ?? Environmental (ISO 14001)
- ?? Safety (OHSAS 18001)

?? Human food safety (HACCP)

e. Detailed comparisons of Compliance Based Systems vs. ISO 9001 QMS
   ?? Compliance based
      - Regulatory driven: programs and processes aimed at maintaining compliance
      - Reactive: quality issues not considered in business planning function
      - Cost center: quality management is a necessary evil
   ?? ISO 9001 QMS
      - Beyond compliance
      - Proactive: plan for and anticipate quality issues with new processes, products and services
      - Strategic business unit: QMS will (can) add to the bottom line

f. Described why organizations implement a management system
   ?? Improved compliance
   ?? Reduction in liability and risk
   ?? System for prioritizing resources
   ?? Decrease costs
   ?? Market advantage
   ?? Pressure from interested parties
   ?? Continual improvement

4. Mike Merkel, Doane Pet Center – pet food company

a. Outlined strategies of the Doane Pet Care (DPC), and the Pet Food Safety System (PFSS)
   ?? Our mission: the trusted partner of choice for our customers brands
   ?? Our primary responsibility: assure all pet foods and treats we manufacture and distribute are safe and wholesome for pets
   ?? Our means of assurance: DPC's Pet Food Safety System (PFSS)

b. Explained DPC – PFSS Risk-Based Preventive System
   ?? Detailed analysis of pet food processing systems
   ?? Identification of potential food safety hazards and assessment of process and product risks
   ?? Implementation of adequate process control measures including employee training
   ?? Verification and documentation that control measures are rigorously measured
   ?? Validation that prevention systems are effective

c. Presented a flow diagram of their ingredient receiving, storage, and manufacturing system

d. DPC – PFSS key system components explained
   ?? Ingredient quality
   ?? Quality manual
   ?? Sanitation and microbial control
   ?? Integrated pest management
   ?? Control of foreign material
   ?? Traceability
   ?? Validation by audit

?? Continuous improvement

e. DPC – PFSS ingredient integrity assurance explained
?? Vendor Q.A. program certification
?? On site inspection
?? Sampling and analysis of shipments
?? Plant mycotoxin testing and rejection capability
?? Vehicle inspection and bottom sampling

f. DPC – PFSS sanitation and microbial center explained
?? Plant specific sanitation schedule and SSOP's
?? Controlled movement of employees and materials
?? Sensitive ingredient pre-delivery test and certification
?? Microbiological monitoring and plant-specific environmental micro mapping
?? Technical services laboratory capable of pertinent pathogen analysis

g. DPC – PFSS traceability system explained
?? Lot number on bagged ingredients
?? Bin designation and origin information on received ingredients
?? Printed code date and mock trace and retrieval on finished products
?? Ingredient receipt and production archive documentation included in audits

h. DPC – PFSS audits and continuous improvement strategy explained
?? Internal GMP / FS audit at all plants
?? External GMP / FS audit at all plants
?? Customer quality audits
?? Continuing education program on use of protein products, public health, security, and bioterrorism

5. **Michael Davidson -** California Department of Food & Agriculture – State feed safety regulatory program

a. Provided an explanation and purpose of the Safe Animal Feed Education (SAFE) Program 2003 in California
?? Provide education and outreach
?? Maintain a website with safety and feed quality assurance information
?? Continue the voluntary feed quality assurance inspections

b. Presented information about reasons for a SAFE program in California
?? First legislative charge: ***"Enable the feed and feeding industry, with the aid of the state, to ensure in every way possible a clean and wholesome supply of meat, milk, and eggs for the benefit of the consumer."***

c. SAFE Program contents outlined
?? Provide feed quality assurance training in cooperation with the California Grain & Feed Association
?? Produce a feed quality assurance manual or video cassettes for firms to provide onsite training
?? Provide feed quality assurance training for on-farm manufacturers, especially for dairies
?? Source of continuous education for purchasers of commercial feed ingredients

?? Conduct voluntary feed quality assurance inspections at feed mills throughout the state
  - Checklist has been revised six times form addition of items such as biosecurity, etc.
  - AAFCO members have been highly involved on feed safety inspections.
  - AAFCO Checklist for Best Management Practices Guidance Document is posted on website *aafco.org*
  - California Commercial Feed Quality Assurance Program Checklist. posted on website *cdfa.ca.gov/is/safe*
  - Canadian Food Inspection Agency, Commercial Feed Mill Inspection posted on website *inspection.gc.ca*

d. Feed safety regulations were discussed with respect to how they are being used and appraised
?? State and U.S. FDA Investigators and industry quality assurance personnel could perform inspections and provide input on the strengths and weaknesses of a proposed US FDA checklist.
?? Next month they plan to have an inspection team use the AAFCO checklist along with the California checklist to identify strengths and weaknesses of each.

6. **Dennis Byrne,** Herr Angus Farm
   a. Presented information and provided insight on how a producer of crops and animals viewed feed safety issues, and related pertinent aspects of their operation to consumer markets
   b. Discussed the Herr Angus Farm operation and addressed feed quality concerns and importance
   c. Provided on overview of the 375 retail food products they sell, such as chips, etc. and related feed/food safety concerns and importance
   d. This crop and animal production operation in Pennsylvania illustrates a pragmatic example or model in place for tying together the needs, concepts, and procedures to link feed safety all the way from seed-to-feed, commodities from feed manufacturing-to-animals, and from feedstuffs and animal products-to-consumers.

7. **Dr. Richard Wood**, Food Animal Concerns Trust – Consumer perspective
   a. Presented information and concepts about consumer issues and the Food Animal Concerns Trust
   b. Outlined issues related to the support for interventions inside the farm gate.
   ?? Processing has been the primary intervention point for addressing food safety.
   ?? Its impact on foodborne disease is mixed.
   ?? Slaughter and processing steps need to be combined with preharvest controls
   ?? A farm-to-fork food safety system must include interventions within the farm gate
   c. Identified what risks to food safety and human health that must be addressed in a comprehensive feed safety system
   ?? Bovine spongiform encephalopathy
     - Close the loopholes
     - Fully enforce the feed ban
   ?? Pathogens in feed

- Establish surveillance of animal feed for microbial contamination
- Establish HACCP programs across the animal feed industry
- Implement a Salmonella-negative standard for animal feed

d. Discussed priority feed safety risks
- ?? Feed additives
  - Drug residues from medicated feeds leftover in equipment that may contaminate the next batch
- ?? Non-therapeutic antibiotics use guidelines need to be routinely used
- ?? Alternative additives such as enzymes, antibodies, phages, and competitive exclusion bacteria
- ?? Contaminants of feeds or feed ingredients
  - Chemical: dioxins, PCB's, pesticides and other agrichemicals
  - Heavy metals: lead, mercury, and cadmium
  - Mycotoxins: toxic substances produced by molds
- ?? Source material of greatest risk
  - Downers as a feed protein source
  - Use of reclaimed industrial wastes
  - Use of recycled animal waste

e. Outlined components of a comprehensive feed safety system
- ?? Establish a mix of voluntary actions and regulations
- ?? Enforce the current feed related policies of FDA
- ?? Require the "riskiest" materials to have the greatest regulation
- ?? Provide an integrated surveillance system
- ?? Act within a transparent decision-making process
- ?? Recognize that a comprehensive Animal Feed Safety System does not stop at the feed distributor's door

BREAKOUT STUDY GROUPS: Participants were placed in one of twelve (12) different breakout groups of approximate equal size and asked to discuss the concept of an Animal Feed Safety System by answering prepared questions. Each breakout group had a preselected group facilitator and a scribe. Information given to each participant stated the questions to consider; that the FDA is seeking information on the Animal Feed Safety System concept and would appreciate everyone's participation and ideas; and that each group should identify a spokesperson to give the group's report and someone to record the group's answers on a flipchart. (Flipcharts and pens were provided.)

Each of the questions given to the breakout groups are stated below, followed by collective responses received for that question.

Question # 1 – ***What feed safety programs are operating today (industry and government) and can they be made available for review by the FDA?*** Responses:

a. Safety programs operating today.
- ?? AFIA Feed Quality Systems
- ?? NGFA QA Program
- ?? California SAFE Program
- ?? Pennsylvania Egg Quality System

- ?? USDA Certification Program
- ?? AAFCO Guidance for Feed Manufacturers
- ?? Kansas State HACCP Program
- ?? Company QA programs driven by insurance/liability concerns
- ?? Texas uses GMP guideline and BSE checklist
- ?? Pork Quality Assurance Program
- ?? Maryland Egg Quality Assurance Program
- ?? Beef Quality Assurance Program
- ?? CODEX Alimentarius Feed Safety Program
- ?? American Protein Producers Industry Certification Program
- ?? Facility Certification Institute
- ?? Animal Nutrition Agency of Canada
- ?? National Oilseed Processors Assn. Process Controls Program
- ?? Canadian Feed Inspection Agency
- ?? Renderer's Association – Model HACCP Program

b. Safety programs available for review by FDA
   - ?? NGFA and AFIA BMP Transportation Training Draft Document
   - ?? Beef Quality Assurance Program
   - ?? Pork Quality Assurance Program
   - ?? Egg Quality System
   - ?? Dairy Herd Improvement System
   - ?? Some breakout study groups felt most of the safety programs in use are available for review by the FDA

Question # 2 – ***What do you think are the basic elements of an Animal Feed Safety System?***
Responses:

a. The AFSS should be easily understood, easily measured, and easily enforced
b. Need to identify scope and risk to humans and animal health
c. Focus on products that can be controlled
   - ?? Thorough analysis of manufacturing and distribution for each product
   - ?? Identify risks associated with the process and product
   - ?? Identify and implement controls to effectively prevent identified risks
   - ?? Employee training programs
   - ?? Focus controls on critical steps
   - ?? Assurance that steps are accurately and consistently performed
   - ?? Record keeping and validation of the system
d. Sampling procedures for individual commodities and complete feeds
e. Ability to sample and regulate feeds mixed on farms
f. Measures to assure security of commodities in transport
g. It should be science based, formalized assessment process
h. Should be comprehensive and look at all sectors
i. Guidance and education component for use in identifying specific risks/hazards to various industry sectors
j. Need clear focus of outcome of feed safety generic – what do you have to have
k. HACCP based program – risk assessment program – written and justified

l. Enforceability
m. Should have standard of methods and tolerances
n. Traceability and trackability verification

QUESTION # 3 – ***What are the benefits of having a federal Animal Feed Safety System?***
Responses:

a. Consistency from location to location is a direct benefit, but is very difficult when states have different requirements
b. It should reduce duplication of efforts on both the states and federal systems
c. AAFCO program is GMP based. States will consult with industry on an educational approach
d. Can develop uniform training with the desired goal of uniform application and equitability
e. Provides an opportunity to develop authority for on-farm and other sectors not currently regulated
f. It would benefit food safety
g. Enhance consumer confidence
h. Help the U.S. with international trade
i. Promote better science or more science which will require/produce more science
j. Reduce conflicting or variations in regulatory requirements
k. Could enable the setting of an official standards "bar" that could cover all segments of the feed industry, large and small
l. Better coordination between Agencies for better utilization of resources
m. Allows consumers to have a better understanding of the industry, and this will help increase consumer confidence

The Notice of Meeting identified 7 items that FDA considered as possible elements of an Animal Feed Safety System. Please answer questions 4(a) through (h).

QUESTION # 4a – ***How much of this are you doing as a firm right now?*** Responses:

a. Mixer validation
b. Sampling and testing of ingredients and complete feeds
c. Packers and sale barns are requiring producers to sign statements saying that there are no violative residues and cattle have not been fed prohibited meat and bone meal
d. Written specifications for ingredient suppliers and supplier audits
e. Most companies are doing something on assessment of risk for products and/or processes
f. Traceability as a part of ISO
g. Companies vary greatly in the types of QA programs they have. They tend to address risks as they see them and are primarily oriented to those risks that would result in direct economic effects or in legal actions
h. Keeping records as required on medicated feeds
i. Third party audits

QUESTION # 4b – ***Is it formal, i.e., written policy and procedures, or informal?*** Responses:

a. Industry has both formal and informal policies
b. Formal policy

c. The attitude is – "if it isn't written down, it isn't done"
d. Depends on the segment of the industry
e. Rendering industry has a lot of it written down
f. Some institutions have many procedures in writing that are not necessary and are not implemented or are not addressed by employees
g. Related to the size of the farm/producer/manufacture and could be influenced by corporate oversight

QUESTION # 4c – ***Would this involve training and what kind would be best and how often?*** Responses:

a. Yes, training is critical
b. State programs do not have formal training programs, but AAFCO provides training
c. Would have to re-write every state law to take the program on-farm
d. Use university extension services for on-farm training
e. Education will be a huge effort
f. Should be something like the HACCP Program
g. Training for record keeping (HACCP based system)
h. Train management for validation aspects
i. Training could be voluntary, mandatory, quarterly, on the job training, or in the classroom
j. Design your own training program
k. Training should be vertically integrated: consumer ? producer ? feed mill
l. National or regional training conferences

QUESTION # 4d – ***Would this involve the purchase and use of new equipment and/or software?*** Responses:

a. In the front end, the industry would need to purchase equipment/software
b. Need internet training, may need software
c. No, not in the U.S.

QUESTION # 4e – ***What kind of costs do you think this will entail?*** Responses:

a. There will be costs for training government
b. Costs will be associated with the risks
c. Not much
d. Cost of third party audits
e. Certification cost
f. Political cost (intangible – can't put a cost on it)
g. Unknown

QUESTION # 4f – ***What kind of assurances would you need to establish or demonstrate this is functional?*** Responses:

a. Education – cooperation
b. Training
c. Record keeping and paperwork are necessary
d. Through testing results and record keeping
e. Internal and external audits

f. Actual occurrence/outcome
g. Customer audits
h. Bring in QA people
i. Depends on the firm and process
j. Government based inspection program would provide the best consumer confidence

QUESTION # 4g – ***How to you envision risk being introduced into the AFSS? Should the risks be identified by industry or government or both?*** Responses:

a. Has to be done by both industry and regulators and must be science-based
b. Must measure risk by science
c. Determine risks by government and industry-negotiated rule making
d. Objectivity may be an issue
e. Conflicting views of this
f. If a comprehensive system is going to be put in place, there must be a consensus of what the risks are

QUESTION # 4h – ***Are current enforcement tools adequate?*** Responses:

a. Federal government could use warning letters, untitled letters, seizures, injunctions, and prosecutions
b. Needs to be to all segments – need to be better allocated
c. Enforcement tools need to be consistently and evenly enforced
d. Some states don't envision playing a major role in this endeavor simply because they don't have the resources
e. There are inadequacies with the current FDA enforcement authorities. FDA does not have the ability to stop sale or withdraw from distribution of potentially adulterated products
f. Authority is there, but we don't have enough resources

QUESTION # 5 – ***In conclusion, are there any additional thoughts or comments this group would like to convey to FDA regarding an Animal Feed Safety System?*** Responses:

a. Make sure all firms are covered: hobby farms to corporate farms and make sure the truckers/haulers are covered
b. Phase in regulations so that small entities can come up to speed with regulations
c. Recognize the complexity of the different systems within the industry
d. Attention needs to be given to materials taken out of feeds and the procedures for disposal
e. FDA and AAFCO need to merge programs together
f. Bring all interested parties to the table as often as possible
g. Shift from economic analysis to safety analysis
h. The AFSS should be easily understood, easily measured, and easily enforced
i. AFSS could have an economic impact on small producers
j. AFSS could result in possible loss of state feed programs
k. There may be difficulty with the enforcement
l. AFSS could have an impact on other Agency's programs
m. AFSS could create an unfair competitive advantage with domestic vs. imported products

n. The program should define the goal and measure the goal, not the method for attaining the goal
o. Tell me what the risks are, and I will be better able to respond

GENERAL CONCLUSION STATEMENT

The Food and Drug Administration (FDA) public meeting conducted to discuss the potential development of a comprehensive, risk-based Animal Feed Safety System (AFSS) was highly successful in facilitating input from a rather broad based representation of people from the feed industry, and state and federal people. Many thoughtful ideas, suggestions, and recommendations were received and compiled by the FDA. Although, as expected, not all ideas and opinions related to the need, direction, and how to establish a national feed safety system were in agreement, but most were supportive and felt the long-tem benefits would out weigh the negatives.

One of the most frequently voiced concerns centered around how to implement and maintain daily operations, on an equitable basis, across a level playing field through all segments of the U.S. animal feeding industries. If a system can be developed that will ensure uniformity, and is successful in identifying and reducing hazards in the U.S. food supply, it will be of great value to animal agriculture and agriculture in general.

Presentations were will prepared and delivered with enthusiasm and pride in light of the overall long-term history of safe animal feed in the U.S. Various presenters demonstrated the attributes and strengths of different components of state-of-the-art quality assurance concerns. While great progress has been achieved by some operations, none were quite at the level of the comprehensive risk-based Animal Feed Safety System being discussed at this meeting.

Results of the breakout study groups were great. The system of assigning groups and sequencing questions was well thought out and delivered the feedback needed. Different groups studied some questions more in depth than others and vice versa. Moreover, excellent and broad responses were received on all questions asked. Breakout group facilitators and scribes were invaluable in generating and capturing information from this part of the meeting.

Finally, overall interest, attendance, participation, and responses relative to discussion of the potential development of a comprehensive, risk-based Animal Feed Safety System (AFSS) were gratifying, and indicate a need to continue efforts in facilitating further broad-based discussions on a national basis. The vision for a system such as AFSS is notable and potential benefits are great.